Our Vision

Establish Lavipharm as an Innovative Formulation and Particle Design Company with Expertise in Molecule Transport

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Lavipharm's Positioning

Drug Discovery → **Pre-Formulation Development** → **Dosage Formulation Development**

Molecule Design

- Organic Chemistry
- Biotechnology
- Combinatorial Chemistry

Lavipharm Field of Activity

Formulation/ Particle Design

- Physical Chemistry
- Physics
- Chemical Engineering

Drug Delivery Devices

- Pharmaceutics
- Physical Chemistry
- Chemical Engineering
- Clinical Science

9 competitors **120-130 competitors**

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Strategy

Target Market

- Pharmaceutical, biotech companies
- New Chemical Entities
- Commercially marketed products facing patent expiration or lifecycle management issues

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Strategy

- Partner early to optimize delivery and economics
- Development through prototype
- Feasibility studies tied to full development (if successful)
- Opportunistic internal development (based on real market needs)

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Health. Innovation. People

R&D and Commercial Challenges

- Solubility of small molecules, peptides/proteins
- Impaired bioavailability
- Particle size & distribution
- Half-life of proteins / peptides
- Optimal delivery
- Life-cycle management
- Patent expiration

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Health. Innovation. People

Lavipharm Laboratories, Inc.

USA

Located near Princeton, NJ, in the heart of "Pharmaceutical Corridor"

Facilities

- 27 Acres of land
- 50,000 sq. ft. building
- Houses Management and R&D team
- Lab and Pilot Plant

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France

Vannes – Hitex 100% ownership
- SCF Scale Up
- Extraction
- Commercial / Industrial Production

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USA

Lavipharm owns 30% of Phasex and perpetual and exclusive rights to Phasex proprietary technology for Pharmaceutical and Cosmetic applications

Phasex is a leader in development of industrial applications for SCF technology

- Polymer Design & Processing
- Lab Scale SCF equipment

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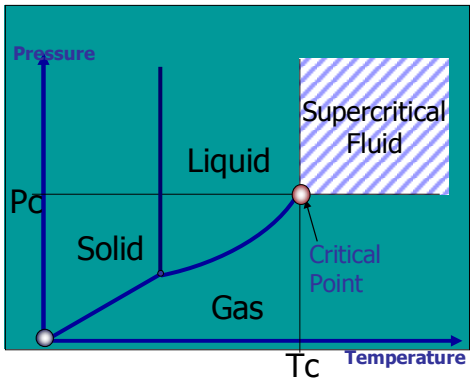
SCF principle



- CO_2 most commonly used
  - Non-toxic
  - Non-flammable
  - Readily available
  - High purity
  - Low Tc / Pc
- PX1 Unique to Lavipharm

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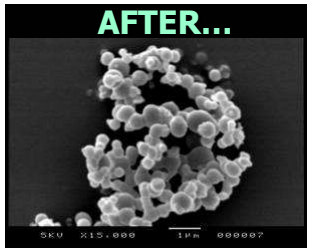
Particle Design

Impaired Absorption
Sub-optimal Bio-availability
Higher Dose Required
Side Effects



Impaired Absorption
Increased Bio-availability
Lower Dose Required
Fewer Side Effects

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Drug Delivery Devices

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Drug Delivery Capabilities

- Oral Controlled-Release Systems
- Transdermal Drug Delivery Systems
- Intra Oral Delivery Systems
  - Quick-Dis™
  - Slow-Dis™
- Topical Drug Delivery Systems
  - "Solid gel"
  - "Liquid patch"

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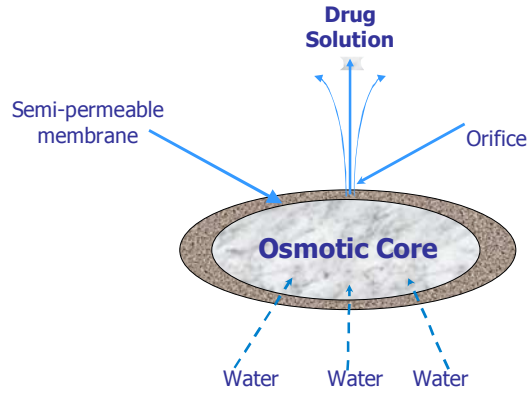
Oral Controlled Release Systems



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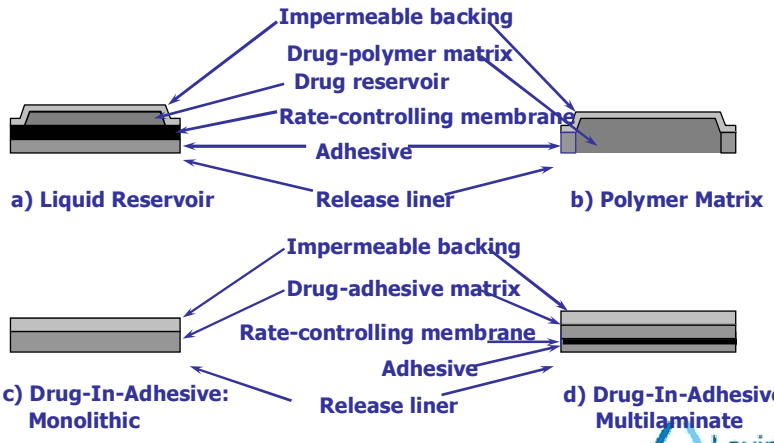
Transdermal Drug Delivery System Designs



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Advantages of Transdermal Delivery Systems *vs* Classical Oral Dosage Forms

- Protection against environment
- Resistance to wash-off *or* rub-off
- Better permeation
- Accurate and controlled delivery
  - Right dose
  - Right place
  - Right time
- Reduced application frequency, longer duration

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Lavipharm´s TDDS Advantages

- **Proprietary permeation enhancer technology**
  - Allows for a smaller patch size
- **Solid reservoir technology**
  - Thinner patch with better aesthetics
- **Better adhesion, lower irritation, better aesthetics**
  - Improved patient compliance

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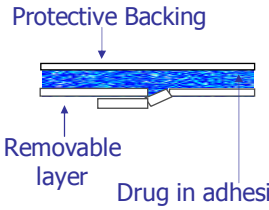
Lavipharm's Nitroglycerin Transdermal System

3rd Generation Technology



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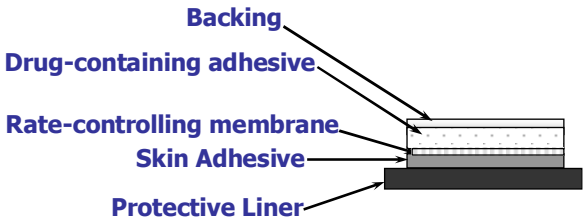
Lavipharm's Fentanyl Transdermal System

Solid Reservoir System with rate-controlling membrane



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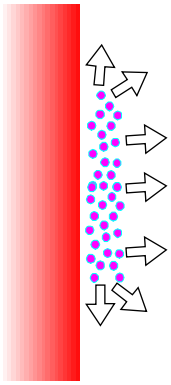
IODS Quick-Dis™



- **Fast-dissolving**
- **Suitable for oral pre-gastric, oral gastric, oral local or sublingual administration**
- **Dissolution time: 10 to 30 sec**

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Quick-Dis™ Special Features

- Flexible, thin and elegant film
- Convenient dosing
- Fast disintegrating
- Quick dissolving
- Good organoleptic properties
- Applicable to wide range of therapeutic drugs
- Ideal for pediatric, geriatric and veterinary applications, etc.

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Quick-Dis™ Patient Benefits

- Quick onset of action
- Improved effectiveness
- No swallowing necessary
- Can be taken without water
- Can be taken discretely
- "Different" *vs* competitive offering

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Taste masking

•Taste-masking is a major challenge involved in formulation of any quick-dissolving dosage form, the Quick-DisTM being no exception.

•Lavipharm has developed proprietary complexation technologies that can be incorporated in the Quick-DisTM to achieve taste masking when needed.

•Subsequently, the formulations can be optimized for taste using conventional flavors and sweeteners.

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Quick-Dis™ Taste masking

- **Conventional Approaches**
  - Microencapsulation
  - Flavors & Sweeteners
- **Proprietary Technologies**
  - Drug / Excipient Complexation

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Intellectual Property

• In order to maintain its competitive position, Lavipharm relies heavily on its technological innovations.

• In addition to protecting its know-how and trade secrets, Lavipharm is the owner of:
> 60 issued patents and
> 50 pending patent applications worldwide

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Sponsored programs

PROGRAMS	DURATION
BRITE - EURAM II BE 3621 Molecular and Nano-Scale Drug Delivery Systems	5/97 - 10/2000
EPET II DIATRO-40 Phyto-chemical control and bioavailability of the ingredients, deriving from different varieties of olives trees and tomato	11/97 - 5/2001
EPET II (146) The design and development of innovative, long lasting action therapeutic systems	10/98 - 3/2001
EPET II (104) Development of protein engineering methods in the production of proteins and other biomolecules of medical and biotechnology interest	11/98 - 2/2001
PAVE (279) Development of amphiphilic hydrogels for controlled-release drugs	1/99 - 12/2000
YPER (97YP 226) Development and *in-vitro* validation of controlled-release spherical drugs using experimental design	1/99 - 12/2000
YPER (97YP 227) Application of *in-vivo*/*in-vitro* correlations in the development of prolonged release pharmaceutical forms	1/99 - 12/2001
PAVET 2000 (00BE308) Development of biologically active products with anti-microbial and healing action from plants of traditional medicine	6/2001-6/2003
ACTAPHARM (QLK3-CT-2001-01783) Novel sources of Actinomycetes diversity for detection of antimicrobial agents with pharmaceutical applications	10/2001-9/2004
EPAN 2003 (YB/76) New directions in immune-therapy of disseminated sclerosis using innovative active cyclic analogs of 87-99 epitope of the basic protein of myelin, alone or coupled with mannane	9/2003-2/2006
ΕΡΑΝ (05ΑΣΒΕΠΡΟ-32) Evaluation of the estrogenic activity of natural origin molecules and their analogs: Development of innovative pharmaceutical	4/2006-4/2008

Thank you

www.lavipharm.com

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